K042606

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SYNTHES®

3.0 Summary of Safety and Effectiveness Information [510(k) Summary]

MAY 27 2005

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Synthes (USA) Titanium Wire
CLASSIFICATION:	Class II § 21 CFR 878.4495: Stainless Steel Suture
PREDICATE DEVICE:	Synthes Titanium Wire
DEVICE DESCRIPTION:	The Synthes Titanium Wire with Barb is a nonabsorbable, monofilament, sterile surgical wire with an attached barb. The 28 gauge titanium wire with barb is available in a length of 538mm and has a permanently attached stainless steel needle.
INTENDED USE:	Synthes (USA) Titanium Wire is indicated for use in soft tissue approximation and/or ligation, for canthoplasty, canthopexy and/or canthal tendon repair.
SUBSTANTIAL EQUIVALENCE:	Comparative information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 7 2005

Ms. Kathy Anderson
RA Manager
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K042606
Trade/Device Name: Synthes (USA) Titanium Wire
Regulation Number: 21 CFR 848.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: May 16, 2005
Received: May 17, 2005

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K042606

Device Name: Synthes (USA) Titanium Wire

Indications:

Synthes (USA) Titanium Wire is indicated for use in soft tissue approximation and/or ligation, for canthoplasty, canthopexy and/or canthal tendon repair.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042606